Declaration

I, Xi Yongzhi, hereby declare as follows:

The undersigned declares further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

I am the inventor and applicant of the US Patent Application Serial No. 10/534,538.

Although we submitted the polypeptide sequences (Genbank accession number AAK98621) on 19 July 2001 with the US US NCBI-Genbank, however, it had never been published on or after that day because we withdraw it immediately, the information respect the polypeptide was empty until we updated the new information on Feb 8, 2006. The detailed explanations are as follows:

I.Observation on relevant date of the sequences in the present patent.

As we know, US NCBI-GenBank, established by the National Center for Biotechnology Information of National Institutes of Health, collects and arranges numerous nucleotide sequences of genes and the corresponding amino acid sequences provided by biological scientists from every country in the world.

Here, we would like to remind the US examiner that: the date, mentioned in the LOCUS line recorded in the NCBI-GenBank data, is the date when the data is finally published. In most of cases, it is also the date when the data is first published. Another recorded date (see below) is the date when the sequence is submitted with the databank. It should be noticed that the two dates are not guaranteed under laws and the databank does not declare that the two dates are correct. *(the relevant*

original text: "The date on the locus line is the date the record was last made public. If the record has not been updated since being made public, the date would be the date that it was first made public. If any of the features or annotations were updated and the record was rereleased, then the date corresponds to the last date the entry was released. Another date contained in the record is the date the record was submitted (see below) to the database. It should be noted that none of these dates is legally binding on the promulgating organization. The databases make no claim that the dates are error -free." see Ilene Karsch-Mizrachi and B. F. Francis Ouellette. THE GENBANK SEQUENCE DATABASE. *Chapter 3, pp51, last paragraph; in Bioinformatics: A practical guide to the analysis of gene and proteins. Second Edition. Andreas D. Baxevanis & B.F.Francis Ouellette., eds.* Copyright©2001 John Wiley & Sons, Inc. ISBNs: 0- 471-38390-2 (Hardback) ; 0-471-38391-0 (Paper); 0-471-22392-1 (Electronic)). Hence, the time or date for the sequences recorded in NCBI-GenBank is just provided to the reader for reference only, and cannot be used as the law grounds for arbitration.

II. Observation on the inventiveness of the sequence.

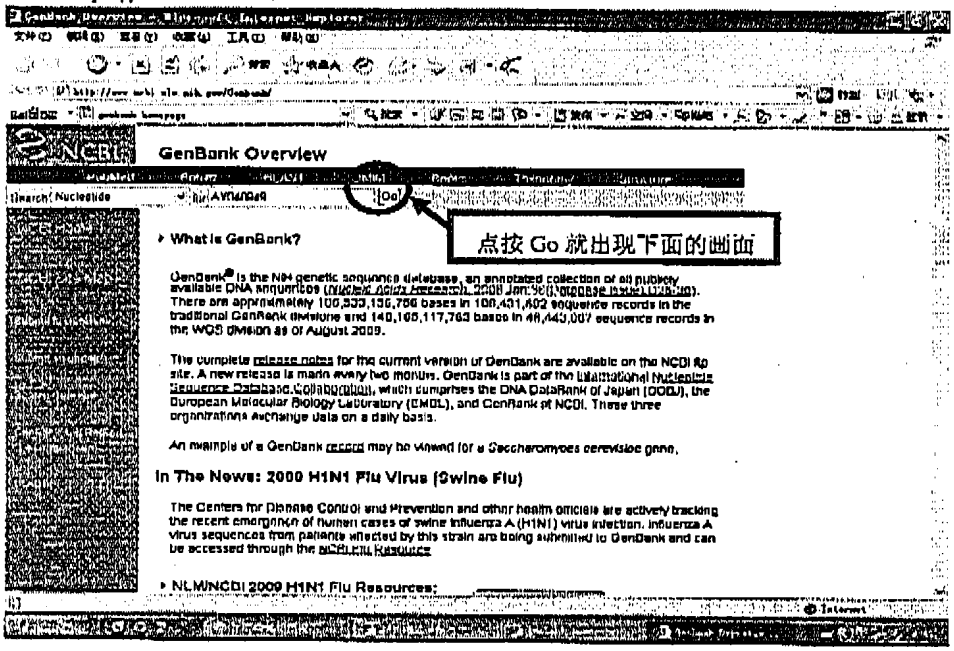
The accession number AAK98621 refers to the amino acid sequence of the chicken type II collagen which is translated by the mRNA (AY046949) of the chicken type II collagen. As we declared in June 29, 2009, AAK98621 and AY046949 indeed were submitted with US NCBI-GenBank on July 19, 2001. However, taken into multiple factors, we withdrew the submission of the two sequences from NCBI-Genbank immediately, and also withdrew the records on relevant sequences in NCBI-Genbank. Only the corresponding accession number and filing date are left. More importantly, NCBI-Genbank does not disclose these sequences (see NCBI-GenBank search page and detailed record Attachments 1 and 2). That is, AAK98621 is formally published on February 8, 2006, much latter than 2002 when the patent was filed. Hence,

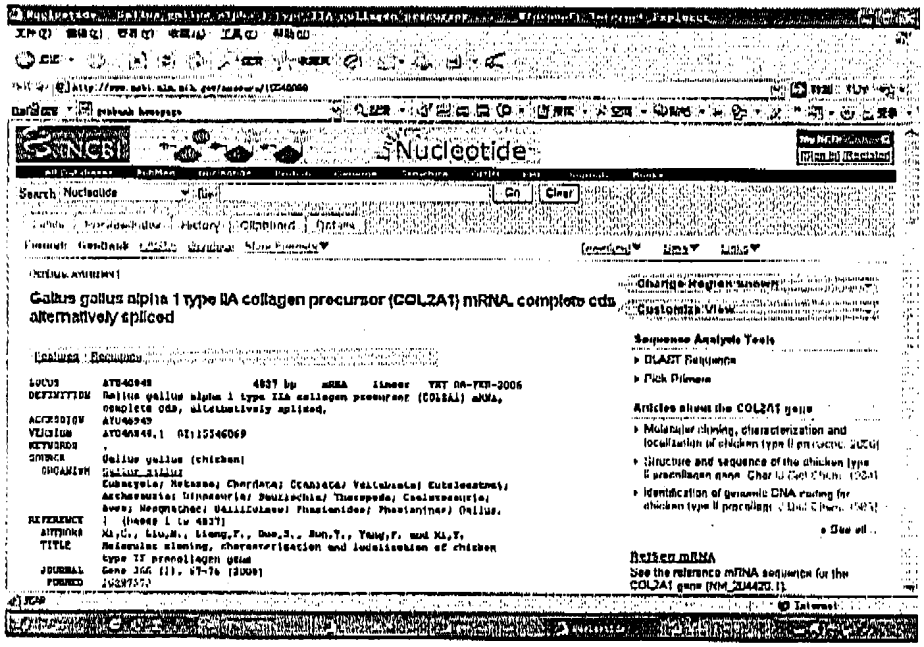
the novelty and the inventiveness of the present patent is not taken away or interfered.

The publication date of AAK98621 and AY046949 are further checked as follows. The search results of all the history records of AAK98621 and AY046949, are separately summarized based on author and accession number:

1. AY046949, version AY046949.1 GI:15546069, is the version of the mRNA of chicken type II collagen submitted on February 8, 2006, with a fragment of 4837bp in length. Although it is shown that version AY046949 is first published on July 19, 2001, no relevant nucleotide sequence can be found in NCBI-GenBank. Namely, the sequence submitted on July 19, 2001 is not published. Its novelty and inventiveness are preserved. AY046949 is formally published on February 8, 2006(see NCBI-GenBank search page below and detailed record attachment 1).

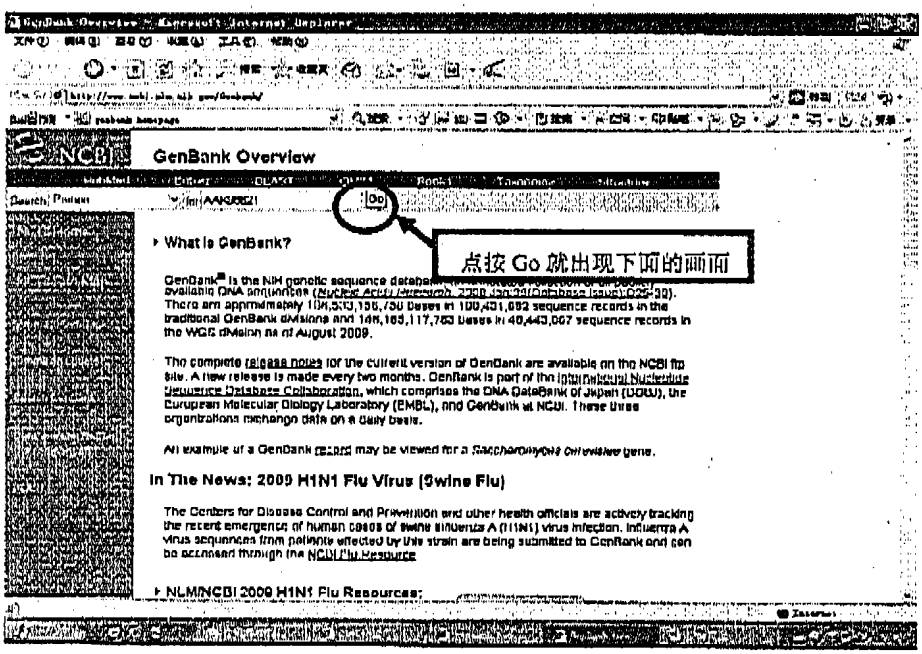
Search page for AY046946

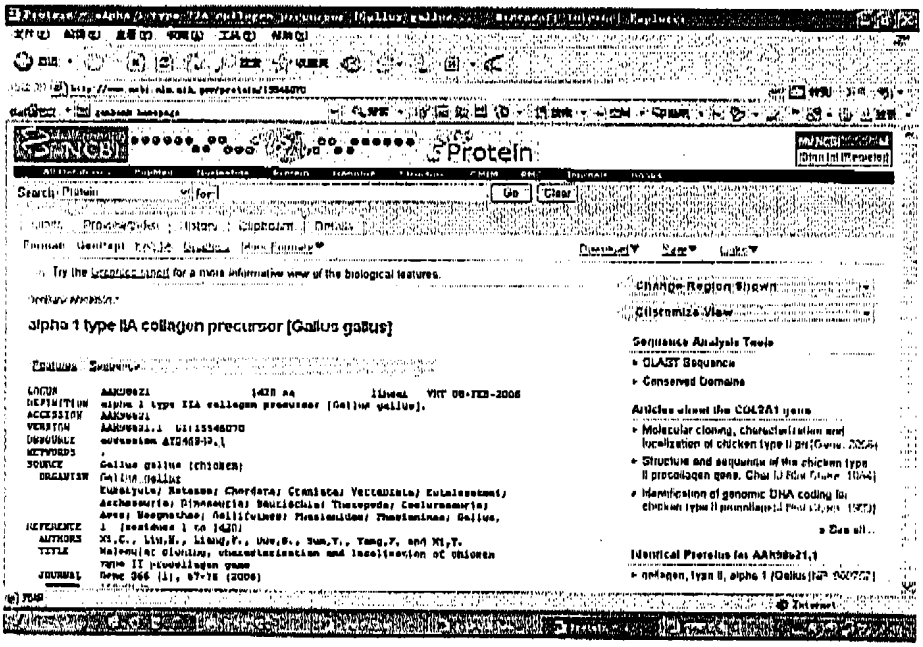




2. AAK98621, version AAK98621.1 GI:15546070, is the version of the amino acid sequence of chicken type II collagen submitted on February 8, 2006, with a fragment of 1420aa in length. Although it is shown that version AAK98621 is first published on July 19, 2001, no relevant amino acid sequence can be found in NCBI-GenBank. Namely, the sequence submitted on July 19, 2001 is not published. Its novelty and inventiveness are preserved. AAK98621 is formally published on February 8, 2006 (see NCBI-GenBank search page below and detailed record attachment 2).

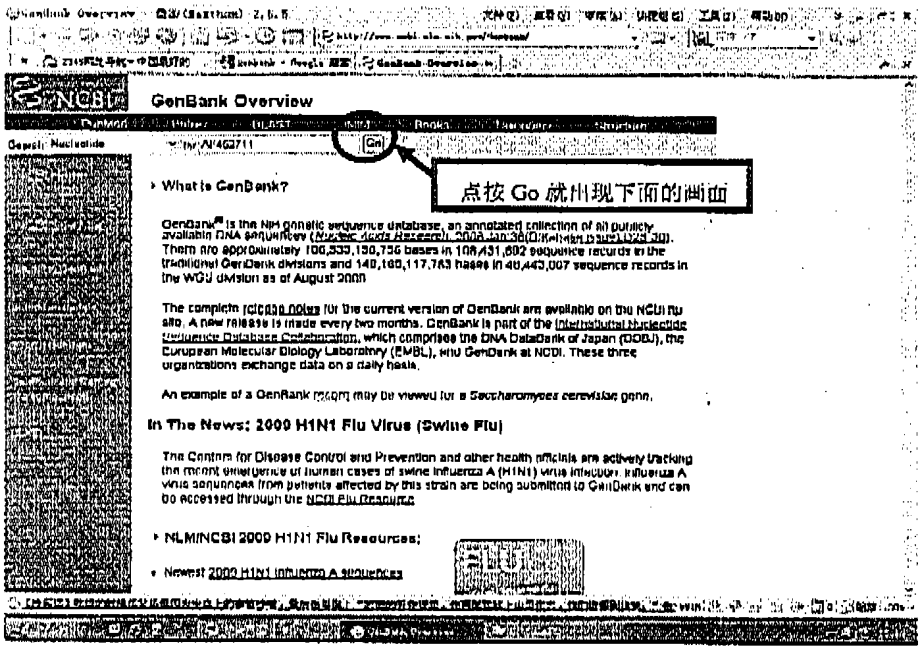
Search page for AAK98621

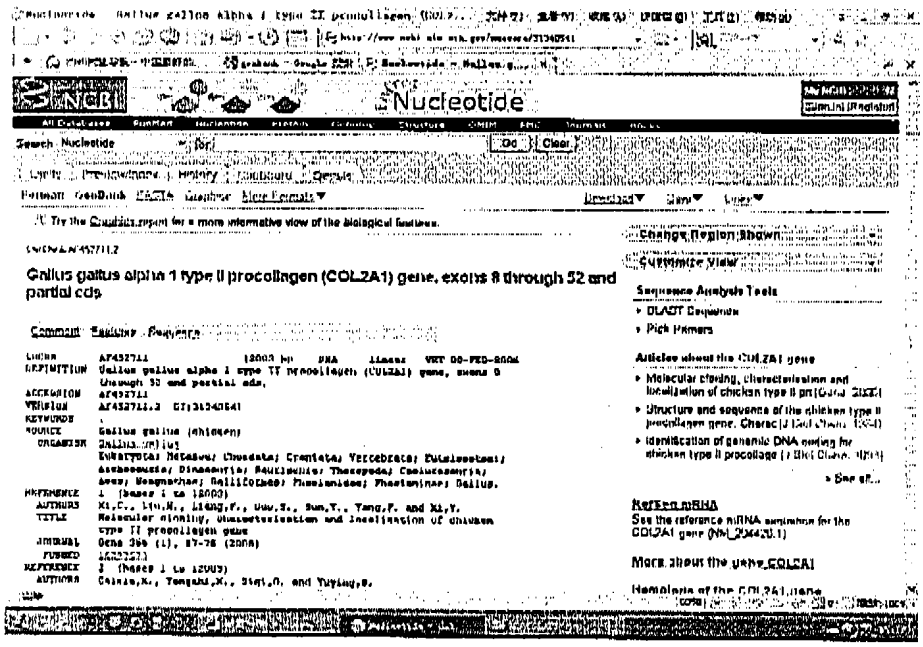

GenBank Overview
Go
点按 Go 就出现下面的画面
What is GenBank?
In The News: 2009 H1N1 Flu Virus (Swine Flu)
NLM/NCBI 2009 H1N1 Flu Resources:


Protein
alpha 1 type IIA collagen precursor [Gallus gallus]

3. AF452711 is the genomic sequence of chicken type II collagen. Version AF452711.2 GI: 31340541, is the newest version of the genomic sequence of chicken type II collagen submitted on February 8, 2006. The fragment comprises exons 8-52 and has 12003bp in length. However, version AF452711.1, updated on June 3, 2003, is part of the genomic sequence of chicken type II collagen, with only 5494bp in length. The two are different by 7509 bp. Although it is also shown that version AF452711 was first submitted on November 27, 2001, just like AY046949 and AAK98621 sequence, no corresponding genomic sequence can be found in GenBank (see NCBI-GenBank search page below and detailed record attachments 3 and 4).

Search page for AF452711





I declare that the above statements are true to the best of my knowledge.

Xi Yongzhi, M.D

November 16, 2009

Nov 17, 2009

Attachment 1: Search record for AY046949, version AY046949.1 GI:15546069

```
LOCUS       AY046949              4837 bp    mRNA    linear   VRT 08-FEB-2006
DEFINITION  Gallus gallus alpha 1 type IIA collagen precursor (COL2A1) mRNA,
            complete cds, alternatively spliced.
ACCESSION   AY046949
VERSION     AY046949.1  GI:15546069
KEYWORDS    .
SOURCE      Gallus gallus (chicken)
  ORGANISM  Gallus gallus
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Archosauria; Dinosauria; Saurischia; Theropoda ; Coelurosauria;
            Aves; Neognathae; Galliformes; Phasianidae; Phasianinae; Gallus.
REFERENCE   1  (bases 1 to 4837)
  AUTHORS   Xi,C., Liu,N., Liang,F., Guo,S., Sun,Y., Yang,F. and Xi,Y.
  TITLE     Molecular cloning, characterization and localization of chicken
            type II procollagen gene
  JOURNAL   Gene 366 (1), 67-76 (2006)
  PUBMED    16297573
REFERENCE   2  (bases 1 to 4837)
  AUTHORS   Caixia,X., Yongzhi,X., Siqi,G. and Yiying,S.
  TITLE     Direct Submission
  JOURNAL   Submitted (19-JUL-2001) Immunology, Beitaipinglu Hospital,
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```

批注: The serial number of the nucleic acid sequence

批注: the sequence of other vertebrate

批注: This is the time when the sequence was submitted for the second time, and also is the time when the sequence was first published.

批注:

批注:

批注: The sequence was submitted for the second time after the paper was published.

批注:

批注:

批注: This is the date when the sequence was first submitted before the withdrawal from the Genebank; but the nucleotide sequence submitted this time was not disclosed, no relevant sequence can be found in Genebank.

批注: AAK98621.1 (the serial number of the amino acid sequence corresponding to AY046949)

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ORIGIN

Nucleotide sequence (mRNA)

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Attachment 2: Search record for AAK98621, version AAK98621.1 GI:15546070

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LOCUS       AAK98621          1420 aa            linear   VRT 08-FEB-2006
DEFINITION  alpha 1 type IIA collagen precursor [Gallus gallus].
ACCESSION   AAK98621
VERSION     AAK98621.1  GI:15546070
DBSOURCE    accession AY046949.1
KEYWORDS    .
SOURCE      Gallus gallus (chicken)
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            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
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            Aves; Neognathae; Galliformes; Phasianidae; Phasianinae; Gallus.
REFERENCE   1  (residues 1 to 1420)
  AUTHORS   Xi,C., Liu,N., Liang,F., Guo,S., Sun,Y., Yang,F. and Xi,Y.
  TITLE     Molecular cloning, characterization and localization of chicken
            type II procollagen gene
  JOURNAL   Gene 366 (1), 67-76 (2006)
   PUBMED   16297573
REFERENCE   2  (residues 1 to 1420)
  AUTHORS   Caixia,X., Yongzhi,X., Siqi,G. and Yiying,S.
  TITLE     Direct Submission
  JOURNAL   Submitted (19-JUL-2001) Immunology, Beitaipinglu Hospital,
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     Region          1148..1174
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批注: The serial number of the amin acid sequence

批注: the sequence of other vertebrate

批注: This is the time when the sequence was submitted for the second time, and also is the time when the sequence was first published.

批注: Corresponding mRNA serial number, the first filing date and the amending date of the sequence are completely consistent with those of AAK98621 (its corresponding amino acid sequence).

批注: The sequence was submitted for the second time after the paper was published.

批注: This is the date when the sequence was first submitted before the withdrawal from the Genebank; but the amino acid sequence submitted this time was not disclosed, no relevant sequence can be found in Genebank.

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ORIGIN

SEQ ID NO: The amino acid sequence

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1201 slrspegskk npartcrdik lchpewksgd ywidpnqgct ldaikvfcnm etgetcvypt
1261 pssiprknww tskfkdkkhv wfaetinggf hfsygdenls pntasiqmtf lrllstegsq
1321 nvtyhcknsi aymdeetgnl kkailiqgsn dveiraegns rftysvledg ctkhtgkwgk
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Attachment 3: Search record for AF452711, version AF452711.1 GI:28190290

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            cds.
ACCESSION   AF452711
VERSION     AF452711.1  GI:28190290
KEYWORDS    .
SOURCE      Gallus gallus (chicken)
  ORGANISM  Gallus gallus
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Archosauria; Aves; Neognathae; Galliformes; Phasianidae;
            Phasianinae; Gallus.
REFERENCE   1  (bases 1 to 5494)
  AUTHORS   Caixia,X., Yongzhi,X., Siqi,G. and Yuying,S.
  TITLE     Gallus gallus alpha 1 type IIA collagen precursor (COL2A1)
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 5494)
  AUTHORS   Caixia,X. and Yongzhi,X.
  TITLE     Direct Submission
  JOURNAL   Submitted (27-NOV-2001) Immunology, Beitaipinglu Hospital,
            Beitaipinglu, Beijing 100039, China
COMMENT     [WARNING] On Jun 3, 2003 this sequence was replaced by gi:31340541.
FEATURES             Location/Qualifiers
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                     /db_xref="taxon:9031"
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                     2174..2227,2325..2432,2701..2754,2864..2971,3106..3159,
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批注: The nucleotide serial number of the genome

批注: the sequence of other vertebrate

批注: the time when it was submitted for the second time

批注: This is the date when the sequence was first submitted before the withdrawal from the Genebank; but the nucleotide sequence submitted this time was not disclosed, no relevant sequence can be found in Genebank.

批注: It was replaced by sequence GI:31340541 on June 3, 2003.

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批注: The serial number of the corresponding amino acid sequence, the first filing date and the amending date of the sequence are completely consistent with those of AF452711 (its corresponding nucleotide sequence).

ORIGIN

批注: The nucleotide sequence (part sequence of the genome)

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Attachement 4: Search record for AF452711, version AF452711.2 GI:31340541

LOCUS AF452711 12003 bp DNA linear VRT 08-FEB-2006
DEFINITION Gallus gallus alpha 1 type II procollagen (COL2A1) gene, exons 8 through 52 and partial cds.
ACCESSION AF452711
VERSION AF452711.2 GI:31340541
KEYWORDS .
SOURCE Gallus gallus (chicken)
ORGANISM Gallus gallus
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Archosauria; Dinosauria; Saurischia; Theropoda; Coelurosauria; Aves; Neognathae; Galliformes; Phasianidae; Phasianinae; Gallus.
REFERENCE 1 (bases 1 to 12003)
AUTHORS Xi,C., Liu,N., Liang,F., Guo,S., Sun,Y., Yang,F. and Xi,Y.
TITLE Molecular cloning, characterization and localization of chicken type II procollagen gene
JOURNAL Gene 366 (1), 67-76 (2006)
PUBMED 16297573
REFERENCE 2 (bases 1 to 12003)
AUTHORS Caixia,X., Yongzhi,X., Siqi,G. and Yuying,S.
TITLE Gallus gallus alpha 1 type IIA collagen precursor (COL2A1)
JOURNAL Unpublished
REFERENCE 3 (bases 1 to 12003)
AUTHORS Caixia,X. and Yongzhi,X.
TITLE Direct Submission
JOURNAL Submitted (27-NOV-2001) Immunology, Beitaipinglu Hospital, Beitaipinglu, Beijing 100039, China
REFERENCE 4 (bases 1 to 12003)
AUTHORS Caixia,X. and Yongzhi,X.
TITLE Direct Submission
JOURNAL Submitted (03-JUN-2003) Immunology, Beitaipinglu Hospital, Beitaipinglu, Beijing 100039, China
REMARK Sequence update by submitter
COMMENT On Jun 3, 2003 this sequence version replaced gi:28190290.
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批注: The nucleotide serial number of the genome

批注: The sequence of other veterbrate

批注: This is the sequence submitted for the last time after the paper was published.

批注: This is the date when the sequence was submitted for the first time; but the nucleotide sequence submitted this time was not disclosed, and no relevant sequence can be found in Genebank.

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7255..7308, 7422..7475, 7744..7905, 7998..8105, 8415..8522,
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